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510(k) Summary - __K080145__

This 510(k) summary of substantial equivalence information is submitted in accordance with the requirements of 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

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42840 Christy Street, Suite 101
Fremont, CA 94538, USA
Telephone: (510) 933-6000
Fax: (510) 933-6001

FEB 28

B. Contact Person

Brian Grigsby
Vice President, QA & RA
Telephone: (510) 933-6090

C. Date Prepared

February 14, 2007

D. Device Name

Trade Name:	Primaeva Medical System
Common Name:	Electrosurgical Unit and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI)

E. Predicate Device

The Primaeva Medical System with reusable Electrode Insertion Device and disposable Electrode Cartridge is substantially equivalent to the Primaeva Medical Finesse System, a legally marketed device (K072261).

F. Device Description

The Primaeva Medical System is comprised of the following components: A reusable radiofrequency (RF) generator with user interface, a reusable cooler controller, a reusable cooling system handpiece, a reusable electrode insertion device and a disposable electrode cartridge. RF energy is delivered from the RF generator through the electrodes into the target tissue.

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G. Intended Use

The Primaeva Medical System is intended for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

H. Technological Characteristics Comparison

The Primaeva Medical System with reusable Electrode Insertion Device and disposable Electrode Cartridge is substantially equivalent in terms of intended use, target population, energy source, principles of operation, etc., to the above noted predicate device.

I. Non-Clinical Test Summary

Non-clinical testing of the Primaeva Medical System with reusable Electrode Insertion Device and disposable Electrode Cartridge included visual and mechanical inspection, electrical and mechanical safety testing, functional performance testing, etc., in bench and/or animal testing.

J. Summary

In summary, the results of non-clinical mechanical, electrical and functional bench and/or animal testing have demonstrated that the Primaeva Medical System with reusable Electrode Insertion Device and disposable Electrode Cartridge meet established design specifications; function as intended; and are considered to be substantially equivalent to the above noted predicate device.

Primaeva Medical Inc. [illegible] www.primaevamedical.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Primaeva Medical, Inc.
% Mr. Brian Grigsby
Vice President, QA & RA
42840 Christy Street, Suite 101
Fremont, California 94538

Re: K080145
Trade/Device Name: Primaeva Medical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 18, 2008
Received: January 30, 2008

Dear Mr. Grigsby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080145

Device Name: Primaeva Medical System

Indications for Use:

The Primaeva Medical Finesse System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080145